Division of Regulated Activities and Compliance

Abbreviations

- BLA: Biologics License Application
- DRAC: Division of Regulated Activities and Compliance
- EOP: End Of Phase
- FDA: Food and Drug Administration
- GLP: Good Laboratory Practices
- GMP: Good Manufacturing Practices
- IDE: Investigational Device Exemption
- IND: Investigational New Drug
- IPT: Integrated Product Team
- NDA: New Drug Application
- PMA: Pre-Market Application
- POC: Point of Contact
- RA: Regulatory Affairs
- RAD: Research Area Directorate
- SAE: Serious Adverse Event
- USAMMDA: U.S. Army Medical Materiel Development Activity
- USAMRIID: U.S. Army Medical Research Institute of Infectious Diseases
- WRAIR: Walter Reed Army Institute of Research

Division of Regulated Activities and Compliance (DRAC)

DRAC supports the development of medical products for the warfighter by providing expert regulatory advice, guidance, and support for vaccine, drug, and device products in all stages of development from tech base to post-market.

DRAC

- What are IND products?
  - Drugs or biologics not licensed for any use
  - Drugs or biologics not licensed for a particular indication
  - Drugs include synthesized or natural chemical compounds
  - They ***CAN*** be probiotics or dietary supplements ***IF*** they are intended for a therapeutic purpose
  - Biologics include vaccines, blood products, targeted antibody treatments
- What are IDE products?
  - Devices not approved or cleared for any use
  - Devices not approved or cleared for a particular indication
  - Devices include diagnostic test kits, instruments, implantable devices, tongue depressors, software, etc.

DRAC
Pharmaceuticals Branch

- Core Responsibilities: Provide regulatory advice, guidance and support for drug development efforts.
- Current Staff:
  - Branch Chief
  - 4 personnel

DRAC
Vaccines and Blood Products Branch

- Core Responsibilities: Provide regulatory advice, guidance and support for vaccines and blood product development efforts.
- Current Staff:
  - Acting Branch Chief
  - 6 personnel

DRAC
Medical Devices Branch

- Core Responsibilities: Provide regulatory advice, guidance and support for medical device development efforts.
- Current Staff:
  - Acting Branch Chief
  - 2 personnel

DRAC

What do we mean by *"Provide regulatory advice, guidance and support*?"

- Determine whether a proposed drug, vaccine, or device requires an IND or IDE.
- Develop regulatory strategies for approval or clearance of the product.
  - Indication for use
  - Numbers and design of phase 1, 2, and 3 trials
  - Is use of the Animal Rule required?
- Identify risk areas for each strategy and provide recommendations to mitigate risk.
- Develop risk mitigation steps for each strategy.
- Serve as the regulatory subject matter expert on the IPT. providing info on FDA's current thinking and processes

DRAC

What do we mean by *"Provide regulatory advice, guidance and support*?"—cont'd

- Serve as the FDA regulatory expert on IPTs and working groups.
- Serve as the central POC for FDA communications:
  - Have informal (e-mail and phone) communications with the FDA.
  - Draft formal communications and review documents to be sent to the FDA.
    - Pre-INDs/IDEs, Initial INDs, IDEs, and 510(k)s
    - IND Information amendments (Clinical, CMC, Pharm/Tox)
    - New protocols and protocol amendments
    - Clinical hold responses
    - Letters of cross-reference and other communications
  - Coordinate formal meetings with FDA
    - Pre-IND/IDE, EOP1, EOP2/Pre-Phase 3, Pre-NDA/BLA/PMA

DRAC
Regulatory Submissions & Medical Writing Branch

- Core Responsibilities: Provide hardcopy and electronic FDA submissions (including IND/IDE/NDA lifecycle management and SAE report submissions), FDA communications support, medical writing services, and document management, and archiving in support of all aspects of regulated product development

- Current Staff:
  - Acting Branch Chief
  - 8 personnel

Challenges

- Budget
  - Considerable time spent on questions/issues/requests that are not from funded products.
  - Some projects not originally identified as requiring regulatory support do require regulatory support, but it was not budgeted for.
  - Reimbursement often not possible or not easily done.
- Communications
  - To/from RA Scientists, internal within USAMMDA, with IPT, and externally.
  - Internal DRAC approach: if any doubt then it is better to send out a message to entire IPT (or other group as appropriate); it's easy to press the "delete" key.